510(k) Summary

ADMINISTRATIVE INFORMATION

JUN 2 7 2013

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, M.D. Chief Medical Officer
Date Prepared:	February 20, 2013

DEVICE NAME

Trade/Proprietary Name:	Axle™ Interspinous Fusion System
Common Name:	Spinous Process Plate
Classification Name:	Spinal Interlaminal Fixation Orthosis
Product Code:	PEK
Classification:	§888.3050
Device Class:	Class II

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/ operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The Axle Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Axle Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

DEVICE DESCRIPTION

The Axle Interspinous Fusion System consists of plates and inserts of various sizes that are used to provide supplemental stabilization of the spinous processes to support fusion. The system components can be assembled in a variety of configurations so that adaptations can be made to take into account pathology and individual patient anatomy.

The systems components are manufactured using standard manufacturing processes of medical grade Titanium alloy (Ti6Al4V) that complies with ASTM F136 – *Standard*

Specifications for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and Invibio PEEK Optima LT-1 in accordance with ASTM F2026 – *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications*.

The implant components are provided clean and non-sterile. These devices are supplied in a rigid sterilization tray and are to be sterilized by a healthcare professional using a Steam Autoclave in accordance with the instructions for use provided by X-spine Systems Inc., as well as the instructions provided by the Autoclave manufacturer.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Axle Interspinous Fusion System is substantially equivalent to the predicate device based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Features

PREDICATE DEVICES

- X-spine Systems, Inc. - Axle Interspinous Fusion System (K101471)
- X-spine Systems, Inc. - Axle PEEK Interspinous Fusion System (K112592)
- Medtronic-Sofamor-Danek–CD Horizon Spinal System Spire Spinous Process Plate (K091445)
- Lanx, LLC – Aspen Spinous Process Fusion Plate (K071877)

PERFORMANCE COMPARISON

The implant components were tested using the following standards:

ASTM F1717 – *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

- Static Compression Bending
- Static Torsion
- Fatigue Compression Bending

In addition to the above standard testing, spike pullout and dissociation tests were performed as part of this submission. There are no cited standards for these tests.

The modified device is used to treat the same indications for use, utilizes the same scientific and operational principles, and is manufactured using the same manufacturing practices from identical materials as the parent device.

In conclusion, X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Axle Interspinous Fusion System modifications substantially meet the performance criteria established by the cleared parent device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

X-Spine Systems, Incorporated
% David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K130438
Trade/Device Name: Axle™ Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: May 30, 2013
Received: May 31, 2013

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130438

Device Name: Axle™ Interspinous Fusion System

Indications for Use:

The Axle Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Axle Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130438